Secrh. II-37—100,000—

H. & P.H. (1948) Department

Ms SERIES.

G.O. No. 1665 P.H

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Dated 20-5-48

[Despatch Abstract.]

Drugs – Draft amendments to the Drugs Rules. 1945 Views of the Govt. Communicated (to the Govt

No.F.1-53/47-D.
Government of India.
Ministry of Health.

New Delhi, the 19th March,48.

From

J.N.Saksena, Esquire, B.A.,
Assistant Secretary to the Government of India.

To

The Secretary to the Government of Madras,
Education and Public Health Department,
M A D R A S.

Sir,

Sub: Draft amendments to the Drugs Rules, 1945.

I am directed to forward a copy of a draft notification containing amendments to Forms 20 and 21 of the Drugs Rules, 1945, and to enquire whether the Provincial Government agree to the Drugs Technical Advisory Board being consulted for the purpose of making the amendments on these lines in the Provincial Drugs Rules. If the Provincial Government agree, the Central Government will consult the Drugs Technical Advisory Board on behalf of itself and the Provincial Government and communicate the views of the Board. In this connection I am to invite your attention to this Ministry's letter No.F.1-56/47-D dated the 13th January, 1948 (copy with copies of encls. closed) and to say that the reference now proposed will be made only if the Board does not recommend the need for wolesale licences for Schedule (1) drugs and drugs other than those in Schedule C. Further action for the amendment of the central and Provincial Rules can be taken after of the views of the Board are obtained. The favour of a very early reply is requested.

I have the honour tobe,
Sir,
Your most obedient servant,

T.N.Saksena.

Assistant Secretary.

Education and Public Health.

Endt. No.21946 G1/48-1 P.H1 dated 25.3.48.

Referred to the Surgeon- General for very early remakrs.

Sd. ....
Assistant Secretary
to Government.

To
The Surgeon-General
with the Government of
Madras.
With enclosures.
to be returned with
reply.

/True Copy/

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NOTIFICATION.

The following draft of certain further amendments to the Drugs Rules, 1945, which it is proposed to make in exercise of the powers conferred by sections 12 and 33 of the Drugs Act, 1940 (XXIII of 1940), is published as required by the said sections for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration on or after the..... Any objections or suggestions which may be received from any person in respect of the said draft before the date specified will be considered by the Central Government.

Draft Amendment.

In Schedule A of the Schedules annexed to the said Rules;

1) For heading of Form 20 the following shall be substituted, namely;-

"LENENCE TO SELL STOCK AND EXHIBIT FOR SALE AND DISTRIBUTE DRUGS OTHER THAN BIOLOGICAL AND SPECIAL PRODUCTS SPECIFIED IN SCHEDULE C".

2) In the heading of Form 21 the word "other" shall be omitted.

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"KP"

Copy of Ministry of Health letter No.F.1-56/47-D, dated the 13th January, 1948, addressed to the Secretary, Drugs Technical ~~Committee~~ Advisory Board.

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Sub: Drugs Rules - Schedule K of the
Modification of - Necessity for.

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I am directed to forward a copy of letter No: 4121/33-H dated the 7th November, 1947 from the Government of Bombay on the subject mentioned above.

The position under the Drugs Rules, 1945 is as below:-

	Import Licence.	Manufacture Licence.	Wholesale dealing Licence.	Retai dealing Licence.
Schedule C drugs.	Yes.)	Yes.)	Yes.	Yes.
Schedule C (1) drugs.	Yes.)	Yes.)	No.)	Yes.)
Other drugs.	No.	Yes.	No.)	Yes.)

(the breackets indicate that the form of the licence is the same).

While Schedule C (1) drugs have been linked with Schedule C drugs for purposes of import and manufacturing licences they have been linked with other drugs for the purposes of sale licence. Althou Rule 122 (e) provides for storage restrictions in respect of Schedule (1) drugs, it is considered that schedule C (1) drugs should be linked with Schedule C drugs for the purpose of sale licence under the Drugs Act.

I am to request that the whole question whether a licence for whosale dealing must insisted upon in the case of all drugs especiallly in the case of Schecule C (1) drugs may be placed before the Board for their consideration at their next meeting and their views together with draft amendmnts to the Rules, if found necessary may be forwarded to the Government of India immediatly after the meeting.

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KP.

Copy of Government of Bombay letter No: 4121/33-H, dated the 7th November, 1947, addressed to the Secretary, Ministry of Health, New Delhi.

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Sub: Drugs Rules.
Schedule K of the-
Modification of-

I am directed to state that, in accordance with para. 16 of the explanatory Memorandum to Government of India, Drugs Rules, 1945, a licence is required for sale by way of wholesale dealing in the case of biological and other special products specified in Schedule C. No. licence is required for sale by way of wholesale dealing in the case of drugs not included in Schecule C. These provisons are embodied in Schedule K to the Drugs Rules - vide item 2 of the same.

2. In the light of the provisions referred to in para. 1 above Form 20 prescribed in the Drugs Rules is confusing. Below this form, there are the following two foot notes:

1) "Note - No licence is required for wholesale dealings in drugs not specified in Schedule C.

2) If the licence is required for wholesale dealings only delete and enter the word 'wholesale'.

Note (2) referred to above seems redundant in the case of Form 20 in.view of the privisons of the rules quoted above.

3. The matter is, however, hot quite clear. Retail dealers have to obtain licences for all products, i.e. in Forms 20 and 21 on payment of a fee of Rs. 5 for each licence. A wholesale dealer in the products included in Schedule C has to obtain a licence in Form 21, on payment of Rs. 5 and he has also to incur the non-recurring and recurring charges for the maintenance of cold storage equipment and suffers loss for products which deteriorate or get time-expired. On the other hand, a wholesale dealer in drugs not specified in Shedule C has a wide range of products fetching larger profits and has no additional expenditure to incur on cold storage facilities, nor has he to bear any appreciable loss by way of deterioration. In these circumstances and in the light of equity and justice, it seems hardly probable that the interntion is to differentiate between the two categories of wholesale dealers. The inclusion of para 2 in Form 25 and para 3 in Form 28 lends support in this view.

Apart from what has been stated above, products other than those included in Schecule C cover all the drugs included in the British and other Pharmaceutical codex and biological and Biochemical products. To allow wholesale dealing in these substances without a licence would appar to frustrate the very objects of the Drugs Act, 1940, and the rules made thereunder. This loophole will enable many firms ro deal in spurious and adulterated drugs by way of wholesale dealing.

4. It may also be pointed out that condition 4 of the Licence Form 20, for sale stocks and exhibition for sale and distribution of drugs other than biological and other special products, clearly specifies that "No drug in Schecule C (1) shall be sold unelss the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in the possession of the licence". The Government of India, Department of Health, in their letter, No: F.4-13/47/D, dated 30th April 1947, have with reference to Rule 64 of the Drugs Rules, temporarily advised storage conditions for the guidance of licensing Authorities and one of the conditions particularly concerning C (1) products is

All Schedule C (1) items generally require to be stored in a cool place, i.e. at a temperature not exceeding 60° F.A. Vitamin

P.T.O.

preparation or preparations containing Liver Extract should be well protected from light and stored in a cool place".

Thus for the preservation of the properties of C(1) items, it is necessary that the storage conditions considered essential by Government should be observed by manufacturers, importers and wholesale and retail dealers, during their transit stocking, exhibition for sale, and distribution, i.e. from the date of the manufacture of the products, to the date of their sale to the consumer.

An importer of the products specified in Schedule C(1) - vide Rule 23 of the Drugs Rules - has to obtain a licence and so does a retailer for such products - vide Rule 61(1) of the Rules - and hence the intention does not appear to be to allow a wholesale dealer in C(1) products to deal in them without a licence, as if he is permitted to do so, Government would be unable to enforce on him condition 4 of the licence in Form 20 and he would be free to abuse the storage conditions as a measure of economy, thereby allowing wilful deterioration of C(1) products during the period he holds them in stock. This would result in the deteriorated products being surreptitiously passed on by a wholesale dealer to a retailer, who, being unaware of the neglect of storing conditions by the wholesale dealer, would stock the deteriorated product according to condition 4 of Licence in Form 20 and sell it to a consumer as a well-preserved genuine product. This would result in a waste of consumers' money and set a problem to the medical profession when such deteriorated C(1) products do not have the desired effect or cause positive harm.

5. In the circumstances stated above, it seems necessary to amend item 2 of schedule K to the Drugs Rules so as to make it obligatory on wholesale dealers in C(1) products also to have a licence in Form 20. I am to suggest that the Government of India may refer the matter to the Drugs Technical Advisory Board

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MEDICAL DEPARTMENT

From

Col. S.L.Bhatia, C.I.E., M.C., M.A,, M.D.(Cantab),
F.R.C.P. (Lond.), F.R.S.(E),
Surgeon-General with the Government of Madras,
Madras 6,

To

The Secretary to Government,
Education & Public Health Department, Madras.

R.No. 26424-D/48, dated ~~xxx~~ 7-4-48.

Sir,

Sub.- Draft amendments to the Drugs Rules, 1945 -

Ref.- Government Endorsement No.21946 G1/48-1 P.H. d/25.3.48.

The Government may agree to the Drugs Technical Advisory Board being consulted for the purpose of making amendments on the lines mentioned in the Government of India Letter No.F.1-53/47-D, dated 19.3.48.

The question of deleting item 2 of schedule K of the Madras Drugs Rules 45 was also raised by this office vide this office letter No. 95349-1 D/47, dated 8-11-47.

The original letter No.F.1.-53/47-D, dated 19.3.48 of the Government of India (with enclosures) are herewith returned.

Your obedient servant,
Sd. N.Rajamanickam,
for Surgeon General with the
Government of Madras.

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MEDICAL DEPARTMENT

From

Col.S.L.Bhatia, C.I.E.,M.C., M.A.,M.D.(Cantab),
F.R.C.P.(Lond),F.R.S.(E),

Surgeon General with the Government of Madras,
Madras.6.

To

The Secretary to Government, Education and Public
Health Department, Madras.

In R.No.26424-D/48, dated 10-5-48.

Sir,

Sub: Draft amendments to the Drugs Rules,1945.

Ref: GovetU.O.Note No.21946 G1/48-2- dated 20-4-48

I have no further remarks to offer in the matter.

your obedient servant,

.....

for Surgeon-General with the
Government of Madras.

(True copy)

GÒVERNMENT OF MADRAS
EDUCATION & PUBLIC HEALTH DEPARTMENT
Letter Ms. No. 1665 P.H.
Dated 20th M a y, 1948.

To

The Secretary to the Government of India,
Ministry of Health, New Delhi.

Sir,

Sub.- Draft amendments to the Drugs Rules, 1945.

With reference to Mr. Saksena's letter No.F.1-53/47-D dated 19t March 1948 on the subject, I am directed to say that this Government agree to the Drugs Technical Advisory Board being consulted on behal of this Government for the purpose of amending the Provincial Drugs Rules on the lines indicated in the draft notification. I am also to say that in the body of Form 20 the word "other" occurring betwee the words "biological and" and "special products" should also be deleted to ~~xxx~~ coincide with the amendment proposed for the heading of the Form.

2. This Government are of the view that the amendments to Forms 2 and 21 now proposed by the Government of India should be considered independent of the question of wholesale licences for schedule ~~20~~ C(1) drugs and drugs other than those in Schedule C, as they are neeessary irrespective of the decision that may be arrived at in th matter of wholesale licences.

/True Copy/

Yours faithfully,

Sd/-
Superintendent
Madras Record Office

MK 24/5/53